(f) [measuring the amount of] detecting bound antibody specific to the equine anemia infectious virus gp 90 envelope antigen in the test sample.--

Claim 2, line 2, after "marker," insert --and--.

Claim 3, line 2, change "polypropilene" to --polypropylene--;

line 3, change "wells," to --wells;--; change "or" to --and--;

line 4, change "or" to --and--;

line 5, after "nylon;" insert --and--.

R E M A R K S

Responsive to the objection raised at page 2 of the Official Action to various informalities in the specification and claims, the text of the specification and claims is amended herewith to correct those and other detected informalities, so as to place this application in condition for disposal at the time of the next Official Action.

The Official Action points out that a certified copy of the priority application was not forwarded by the International Bureau. Accordingly, applicants are requesting a fresh certified copy from Brazil, which will be forwarded to the Examiner upon receipt by the undersigned.

At page 3 of the Official Action, claims 1-3 were rejected under the first paragraph of 35 USC §112, as alleged-

ly being based on a non-enabling disclosure. That rejection is respectfully traversed.

The rejection is based on the Examiner's contention that the specification does not adequately teach how to make recombinant gp90. However, that rejection is defective as a matter of law, because it assumes, without supporting evidence, that those skilled in this art would be unable to make recombinant gp90 based on their pre-existing knowledge. Instead, the Official Action merely offers the conclusory allegation that a skilled artisan would not have the requisite reasonable expectation of success in making recombinant gp90, but that allegation lacks the requisite factual underpinning. As stated for example in *In re Dinh-Nguyen et al.*, 181 USPQ 46 (CCPA 1974), "[a]n assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubt so expressed."

As a factual matter, the contention made in support of the non-enablement rejection is also contradicted by the evidence of record. In particular, the applied PETERSON et al. reference (U.S. Patent No. 5,427,907) teaches that the complete genome of the envelope protein portion of the EIA virus was sequenced at least 14 years ago, from which the complete amino acid sequence of the envelope protein was predicted. Still further, the BALL et al. article ("Detailed Mapping of the Antigenicity of the Surface Unit Glycoprotein

of Equine Infectious Anemia Virus by Using Synthetic Peptide Strategies", JOURNAL OF VIROLOGY, 1992, 66(2), pages 732-742) applied in the outstanding Official Action discloses the full sequence of gp90, as does the applied PAYNE et al. article ("Virology" 1989 Vol. 172 pp. 609-615). From those teachings, together with the relatively high level of skill in this art, it is apparent that the skilled artisan would have no difficulty in making recombinant gp90, as the present inventors have in fact done in *E. coli* and other conventional expression systems.

Conclusive evidence of the impropriety of the non-enablement rejection appears in the applied REIS et al. reference (1996 GENBANK ACC. NO. U53453), which demonstrates that not only is it possible to make recombinant gp90, but also, at the time of the filing of the Brazilian priority application, this had already been done. Therefore, it is irrefutable that those skilled in this art well know how to make the material necessary for practice of the present method. The non-enablement rejection must therefore be withdrawn.

At pages 3-4 of the Official Action, an indefiniteness rejection was applied to claims 1-3 as previously in the case, on the basis of several well-taken formal criticisms of those claims.

In response to that rejection, claims 1-3 are amended herewith as to form, and in a manner that is believed

to make the scope of those claims clear. It is accordingly believed that the rejection of claims 1-3 as previously in the case for indefiniteness, should not be applied to the claims as amended.

At page 5-8 of the Official Action, claims 1-3 were rejected under 35 USC §103 as allegedly being unpatentable over PETERSON et al. (U.S. Patent No. 5,427,907) in view of various secondary references. Those rejections are also respectfully traversed, for the following reasons.

PETERSON et al. discloses an assay similar to that claimed, but one which uses selected portions of the gp45 protein, and not a recombinant gp90 protein, as required by the present claims. Therefore, the secondary references were relied upon for disclosures of the gp90 sequence. The Examiner contended that it would have been obvious to use the gp90 protein of the secondary references in place of the gp45 subregions of PETERSON et al., owing to the known immunogenetic nature of gp90.

The prior art rejections applied in the outstanding Official Action therefore amount to contentions that it would have been "obvious to try" a recombinant gp90 in the process of PETERSON et al. However, as stated by the U.S. Court of Appeals for the Federal Circuit in *In re Dow Chemical Co.*, 5 USPQ 2d 1529 (Fed Cir 1988):

> The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process

> should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art....Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure. (citations omitted, 5 USPQ 2d at 1531).

The Official Action does not identify where in the applied prior art the requisite "reasonable expectation of success" for the allegedly obvious use of a recombinant gp90 in the PETERSON et al. process is to be found. Indeed, when the prior art is examined in that light, quite the opposite conclusion appears.

In particular, the disclosure at column 11, lines 1-6 of the PETERSON et al. patent is dispositive as to the impropriety of all of the prior art rejections applied in the outstanding Official Action. That text reads as follows:

> The envelope protein is cleaved by the virus into two protein portions, known as GP-45 and GP-90. GP-90 is the larger of the two proteins and is known to exhibit antigenic variation, (See Rushlow, et al.), making peptides within this protein unsuitable for use in an immunoassay.

Thus, far from providing any expectation of success, the PETERSON et al. reference emphatically "teaches away" from any method such as that claimed, by emphasizing the expectation of <u>failure</u> in the claimed methods, owing to the known antigenic variation of gp90, such that peptides within the protein were considered altogether unsuitable for use in the claimed methods.

Consequently, it is apparent that PETERSON et al. as a primary reference, plainly cannot support a proper rejection of any of present claims 1-3. Favorable reconsideration and withdrawal of those rejection is accordingly respectfully requested.

In view of the present amendment and the foregoing remarks, therefore, it is believed that this application is now in condition for allowance, with claims 1-3, as amended. Allowance and passage to issue on that basis are accordingly respectfully requested.

Respectfully submitted,

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